

CLAIMS

1. A inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives, comprising butylphthalide and cyclodextrin or cyclodextrin derivative,
5 wherein the molar ratio of butylphthalide to cyclodextrin or cyclodextrin derivatives is 1:1-10.
2. The inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives according to claim 1, wherein said butylphthalide is D, L-mixed or levorotatory butylphthalide.
- 10 3. The inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives according to claim 1, wherein said cyclodextrin is selected from the group consisting of α -cyclodextrin, β -cyclodextrin and γ -cyclodextrin.
4. The inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives according to claim 1, wherein said cyclodextrin derivatives are selected
15 from the group consisting of hydroxyethyl- β -cyclodextrin, hydroxypropyl- β -cyclodextrin, dihydroxypropyl- β -cyclodextrin, methyl- β -cyclodextrin, glucose cyclodextrin, maltose cyclodextrin, meltotriose cyclodextrin, carboxymethyl cyclodextrin and sulfonylalkyl cyclodextrin.
- 20 5. The inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives according to claim 1 or 4, wherein the preferred cyclodextrin derivative is hydroxypropyl- β -cyclodextrin.
6. A process for preparing the inclusion complex of butylphthalide with

cyclodextrin or cyclodextrin derivatives, comprising the steps of adding cyclodextrin or cyclodextrin derivatives into a suitable solvent vehicle to obtain a solution with a concentration of 5-60%, adding butylphthalide into the solution, stirring to obtain a liquid inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives.

7. The process for preparing the inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives according to claim 6, further comprising the step of drying the liquid inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives to obtain a solid inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives.

8. The process for preparing the inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives according to claim 6, further comprising the steps of concentrating the liquid inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives into a solution with a concentration of 10-15% (W/V), cooling to obtain white precipitate, filtering, and drying to obtain a solid inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives.

9. A process for preparing the inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives, comprising the steps of placing the cyclodextrin or cyclodextrin derivatives into a colloid mill or mortar, adding a suitable solvent vehicle to obtain a paste, adding butylphthalide into the paste, filtering, and drying to obtain a solid inclusion complex of butylphthalide with cyclodextrin or

cyclodextrin derivatives.

10. A process for preparing the inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives, comprising the steps of adding cyclodextrin or cyclodextrin derivatives into a suitable solvent vehicle to obtain a solution with a 5 concentration of 5-60%, dissolving butylphthalide into an appropriate amount of ethanol with purity of 99%, mixing the two solutions, stirring, and drying to obtain a solid inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives.

11. The process for preparing the inclusion complex of butylphthalide with 10 cyclodextrin or cyclodextrin derivatives according to claim 6, 9 or 10, wherein said suitable solvent vehicle is selected from the group consisting of water, ethanol, methanol, propanol, isopropanol, ethylene glycol, propylene glycol, glycerin, acetone, or the mixed solvent vehicle of any two or more above solvent vehicles, wherein water is preferred.

15 12. Use of the inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives, wherein the liquid inclusion complex of butylphthalide with cyclodextrin or cyclodextrin derivatives may be directly used to produce liquid dosage forms, such as infusion, injection, injectable powder, liquids for oral administration, syrup, and the like; the solid inclusion complex of butylphthalide with cyclodextrin or 20 cyclodextrin derivatives may be used to produce solid dosage forms, such as tablets, capsules, granules, dispersible tablets, and the like.